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WRITTEN STATEMENT

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MEDICAL INNOVATION: INNOVATION AND PROVIDER/PATIENT PERSPECTIVES

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Computer Aided Diagnosis (CAD) in Mammography

Each year in the US, there are over 200,000 breast cancers diagnosed, and this is the second leading cause of cancer mortality in women. The advent of mammographic screening has resulted in significant improvements in detecting these cancers at an earlier, and therefore, more curable stage.

Mammography remains the only method for detecting breast cancers earlier than clinical examination.

While mammography is currently our best weapon in the war on breast cancer, it clearly has limitations. One of these has to do with the human observer reading the mammogram. In the few studies that have been done, between 25 and 70 percent of breast cancers visible on mammograms could possibly be detected on previous exams. If two radiologists read the same mammogram, improvements from 5 to 15% in breast cancer detection have been documented. However in the United States this is a relatively rare practice, probably less than 5% of all mammograms. The breast cancer issue has also become quite a charged one, and as of 1995 negligence suits for delayed diagnosis of breast cancer have become the #1 medical litigation, and radiologists are the most frequently-sued specialists. Fortunately, there is promising new technology on the horizon that may help to alleviate some of the understandable limitations of human observers, and thereby improve breast cancer care.

For the past 10 years in the Kurt Rossmann Laboratories at the University of Chicago, we

have been developing computer aided diagnostic (CAD) methods in radiology, with an emphasis on mammograms. Studies with both masses and calcifications (the two most common abnormalities on mammograms signaling cancer) have shown that improvements in observer performance using CAD are similar to that of a second reader. As imaging medicine moves into a completely digital era, we eagerly await the advent of full field digital mammography, which is just now in the preclinical trials. We have developed our techniques with this in mind, but CAD can be performed currently by digitizing standard screen film mammograms and applying the computer programs to the digital data. The technology works analogously to a spell-checker in a word processor program, providing visual prompts to the radiologists reading the mammogram to carefully examine suspicious areas. The sensitivity of the procedure is high, in the range of 70 - 90%, comparable to a good radiologist reading the mammograms.

In medicine, there has been increasing use of computerized diagnostic aids, and the future is sure to continue this trend. We have seen the development of automated analysis of complicated electrocardiogram signals become almost routine. The FDA last year gave approval for use of computer diagnostic tools in automated cervical pap smear readings. In general, CAD is designed to aid the human observer and not to replace him or her. The ultimate diagnostic decision still rests with the physician utilizing the computer aid, which acts as a safe guard. In mammography, there are now commercial versions of this type of equipment, being marketed primarily in Europe. Using one of these devices, Dr. Rachel Brem of Johns Hopkins recently reported (at the Society for Breast Imaging meeting in San Diego) improvements in microcalcification detection on mammograms of up to 7%, and the computer flagged 41 of 42 pathologically proven malignant microcalcifications. My own studies on lesions overlooked by

radiologists indicate that the computer can point to about 50% of the cancers missed.

The current systems emphasize detection, or finding lesions on mammograms.

Very promising work under way at our laboratories indicates that significant improvements in characterization of lesions as to their benign or malignant nature can also be performed by the computer. Observer studies using the computer show that virtually all observers can improve their decision making as to whether or not microcalcification clusters seen on mammogram need to be sent to biopsy. The future is to marry the detection and analysis tasks into one integrated system.

Therefore given the importance of detecting early breast cancer, the promise of CAD methods, and the expectation that successes achieved to date can only improve, I think that we will see significant advances in implementing this valuable medical technology, hopefully in the near future. This should save more lives.

Robert A. Schmidt is a minor share holder in R2 Technology, Inc. (Los Altos, CA).